UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, WISCONSIN, THE CITY OF CHICAGO, AND THE CITY OF NEW YORK *ex rel.* OMNI HEALTHCARE INC.,

Plaintiffs,

v.

MCKESSON CORPORATION, MCKESSON SPECIALTY CARE DISTRIBUTION CORPORATION, MCKESSON SPECIALTY DISTRIBUTION LLC, MCKESSON SPECIALTY CARE DISTRIBUTION JOINT VENTURE, L.P., ONCOLOGY THERAPEUTICS NETWORK CORPORATION, ONCOLOGY THERAPEUTICS NETWORK JOINT VENTURE, L.P., US ONCOLOGY, INC., and US ONCOLOGY SPECIALTY, L.P.,

Defendants.

Civil Action No. 1:12-CV-06440 (NG) (LB)

JOINT RULE 26(f) REPORT AND PROPOSED DISCOVERY PLAN

Counsel for Plaintiff-Relator Omni Healthcare, Inc. ("Omni") and Defendants McKesson Corporation and Oncology Therapeutics Network Corporation participated in the meeting required by Fed. R. Civ. P. 26(f), and hereby jointly submit the following report of their planning conference and proposed discovery plan.

I. PARTICIPANTS

The parties conferred by telephone on March 13, 2019. Present during the call were George Carpinello for Relator, and Ethan Posner, Michael Maya, and Giulia di Marzo for Defendants.

II. CLAIMS, DEFENSES, AND RELEVANT ISSUES

Relator's Statement:

This action arises from Defendants' unlawful conduct in connection with its manufacture, distribution and sale of various injectable oncology, anemia, and related drugs ("the Oncology Drugs") in pre-filled syringes for administration to cancer patients undergoing chemotherapy treatment and other immuno-compromised patients. As part of this operation, McKesson purchased original, single-use vials from their respective manufacturers, broke their sterility, pooled the contents, and repackaged the drugs into pre-filled syringes. McKesson profited from this scheme by not only filling syringes with the "single dose" from each vial as intended by the manufacturer, but also by filling syringes with the "overfill", which is put in each vial to ensure a doctor is able to withdraw the full amount of a drug sold. McKesson's pre-filled syringe program allowed them to monetize and profit from the overfill at the risk of harming vulnerable patients who knew nothing about the origins of these drugs and had no idea that McKesson had circumvented important drug safeguards in order to generate illicit profits.

By harvesting the overfill, McKesson was able to create more doses than it bought from the original vial manufacturers. McKesson then billed multiple health care providers for the same exact vial of drug, causing some of those providers to bill Medicaid and Medicare for the same vial more than once. Defendants also caused health care providers to bill for overfill in violation of the law. (SAC, at ¶¶ 214-16). The scheme also enabled McKesson to increase its

market share by offering various product discounts, which it leveraged to obtain new customers and to keep existing customers buying its entire portfolio of oncology drugs.

Defendants' Statement:

Defendants deny Omni's allegations and deny that Omni is entitled to any relief whatsoever. The Department of Justice investigated this case after it was filed in March 2012 and declined to intervene on April 16, 2018.[1] On February 4, 2019, the Court granted Defendants' motion to dismiss in part and denied it in part. The Court dismissed all claims except those brought under 31 U.S.C. § 3729(a)(1) (for allegedly false claims), 31 U.S.C. § 3729(a)(2) (for allegedly false statements), and analogous state statutes. The Court also dismissed all of the named defendants except McKesson Corporation and Oncology Therapeutics Network Corporation.

Omni bases its remaining claims primarily on the notion that preparing single-dose pre-filled syringes containing overfill is *per se* unlawful. That is not correct. This common practice is not only acceptable when undertaken in a manner consistent with applicable rules and guidance (as it was here), but it provides meaningful medical benefits, such as enhancing convenience and reducing medical errors. Defendants are confident that discovery will reveal that the nine-year-old conduct at issue in this case did not violate the False Claims Act or the analogous state statutes identified in the SAC.

III. PROPOSED SCHEDULING ORDER

The parties were unable to agree on a proposed schedule. Each side's position is set forth below.

[1] The Plaintiff states also declined to intervene on May 3, 2018.

Relator's Proposal:

As laid out in more detail in Section IV, Relator disagrees with Defendants' proposal for "phased" discovery and proposes the following schedule for all discovery:

Event	Relator's Proposed Deadlines
Completion of **All Fact** Discovery	January 17, 2020
Service of Relator's and Defendants' initial expert reports	February 17, 2020
Service of Relator's and Defendants' rebuttal expert reports	March 13, 2020
Completion of expert depositions	May 1, 2020
Filing of dispositive motions	June 1, 2020
Trial	60 days following resolution of dispositive motions

Defendants' Proposal:

As described in more detail below, Defendants propose that discovery be phased in this broad and complex action. Defendants propose the following schedule for Phase I:

Event	Defendants' Proposed Deadline
Completion of Phase I fact discovery	January 17, 2020
Service of Relator's expert reports	February 14, 2020
Service of Defendants' expert reports	March 13, 2020
Completion of expert depositions	April 24, 2020
Filing of dispositive motions	May 22, 2020
Trial	60 days following resolution of dispositive motions

IV. PROPOSED DISCOVERY PLAN (FED. R. CIV. P. 26(f)(3))

A. What changes should be made in the timing, form, or requirement for disclosures under Rule 26(a), including a statement of when initial disclosures were made or will be made

The parties have agreed to exchange initial disclosures on or before March 27, 2019.

B. The subjects on which discovery may be needed, when discovery should be completed, and whether discovery should be conducted in phases or be limited to or focused on particular issues

Relator's Statement:

Relator respectfully submits that because Defendants' fraud was nationwide in scope, uniform across all states, perpetrated in the same way from 2001 through at least 2010, and aimed primarily at defrauding the federally funded Medicare and Medicaid programs, that all discovery should proceed at one time with the scope of discovery limited only by the Federal Rules of Civil Procedure and the local rules, and not by Defendants' proposed plan of multiple discovery "phases." Though Defendants are silent about the number of discovery "phases" they are proposing, based upon their representation that they wish to focus on just one state initially because "each of the state Medicaid programs is distinct," and the fact that 31 states are named as plaintiffs in this case, Defendants apparently intend that there be at least 31 "phases" of discovery.[2] Defendants' proposed geographic and temporal limits on discovery are inequitably proposed to apply only to discovery that Relator can obtain from Defendants, and would not

[2] After reading Relator's position, Defendants added language to their response to the effect that they are not asking for "31" phases of discovery, but they still have not specified any number, clearly hoping that if "phased" discovery is granted that they will be able to make seriatim motions to justify dragging the case out for as long as possible. And, as set forth in Defendants' proposed schedule (Section III, supra), Defendants' proposal is not limited to discovery; each "phase" of discovery would be followed by its own motions for summary judgment and its own trial.

apply to any other discovery, including Defendants' defenses based upon, *inter alia*, government knowledge "and when it gained that knowledge." (Defendants' Statement, n.4). Defendants' gamesmanship is apparent and should be rejected out-of-hand.

All of Defendants' arguments seem to imply that Defendants made, and prevailed, on the same arguments in their motion to dismiss and that this somehow limits the scope of Relator's claims against them. For instance, Defendants argue that limiting discovery to Florida "is particularly appropriate given that the only allegedly false claims set forth with any specificity in the SAC are the claims that Omni itself submitted in Florida." But Defendants made no such argument in their motion to dismiss. Relator's claims in the SAC are examples only; no discovery has been conducted. The allegations are nationwide and discovery should be nationwide. Defendants do not make any suggestion anywhere that what they did with Relator is any different than what they did with providers throughout the nation. Furthermore, Defendants' attempt to use discovery limits as a substitute for arguments they never made in a motion to dismiss, and that this Court never granted, should be rejected. Their proposed "phased" discovery should also be rejected for the reasons outlined below.[3]

First, Defendants do not deny that their pre-filled syringes were sold nationwide from 2001 through at least 2010 (Section II, supra); instead, they argue that selling pre-filled syringes was not illegal and that their program was undertaken in a manner consistent with applicable rules and guidance. This defense is inconsistent with Defendants' contention that discovery

[3] Obviously, one reason Defendants seek these limitations is to shield from discovery any of the more contemporaneous evidence of their fraud, which is relevant to Defendants' actions throughout the entire period of their fraud since the complaint alleges and Defendants do not deny that the fraud was an ongoing practice through at least 2010. And again, they provide no factual or legal justification for differentiating discovery (only for Relator's case) based upon the time period and the location of the fraud.

should be phased, limited only to 2007-2008 and focused just on Florida. As set out in the SAC, the applicable "rules and guidance" were promulgated by the federal Food and Drug Administration, and by Medicare and Medicaid, and Defendants' program was perpetrated from centralized manufacturing facilities outside of Florida, and that the manufacturing facilities sold the illegal syringes to unsuspecting physicians nationwide. Thus, there is no basis for Defendants' temporal and geographic limits on discovery.

Similarly, Defendants claim that it "would not be sensible to attempt to litigate claims related to all of these claims, all of these [state Medicaid] programs, and all of these [Medicaid] laws all at once", but there is no basis for this conclusion. And Defendants offer no specifics concerning distinctions between any states' Medicaid laws or programs that would justify separate discovery phases for each state. Defendants also ignore that Medicaid is financed almost entirely by the federal government, while Medicare is a national program administered only by the Federal government Therefore, any "phased" plan would be based upon meaningless distinctions and would unnecessarily bifurcate and prolong discovery on Defendants' fraud, which was carried out in exactly the same way across the nation.

Second, Defendants' assertions in support of its "phased" discovery plan are dependent upon *ipse dixit*, not on facts alleged in the SAC. Defendants claim (without citation) that discovery should be limited to 2007-2008 because "the evidence related to . . . two [of Defendants' illegal manufacturing] facilities—and therefore the two time periods—will be largely distinct" and Relator makes "no specific allegation at all about any conduct at [the Tennessee manufacturing] facility." But the SAC and Relator's allegations of fraud do not support Defendants' assertions. The SAC alleges that McKesson's fraud spanned from 2001 until at least 2010 (SAC, at ¶ 6), and that Relator purchased the pre-filled syringes from 2007

through 2010 (*Id*., at ¶ 215). While the SAC notes that Defendants' illegal manufacturing plant was moved from Texas to Tennessee (SAC, at ¶19) at an unknown date, and that Relator had toured the Texas plant (*id*.) the SAC's allegations are in no way dependent upon the date of the move or the fact of the move to Tennessee, nor are the SAC's fraud allegations linked to Defendants' plant operating either from Texas or Tennessee during any particular time period.

Third, Defendants' proposed discovery plan will needlessly prolong this litigation as highlighted by the fact that the first phase alone of Defendants' fact discovery plan will take exactly as long as **all** fact discovery under Plaintiff's proposed plan. (Section III, supra). Defendants' "phased" discovery is not only inefficient, it is likely to multiply "the number of depositions to be taken, increasing discovery burdens and delaying the case's ultimate resolution." *Lewis v. Bellows Falls Congregation of Jehovah's Witnesses*, No. 1:14-CV-205, 2015 WL 4603366, at *2 (D. Vt. July 30, 2015) (rejecting a phased discovery plan).

Fourth, the cases cited by Defendants stand for the proposition that phased discovery is instituted only in cases where a defendant offers proof that "nationwide discovery would be either overbearing or cost-prohibitive." *U.S. ex rel. Spay v. CVS Caremark Corp.*, No. CIV.A. 09-4672, 2013 WL 4525226, at *7 (E.D. Pa. Aug. 27, 2013) (limiting the temporal scope of discovery to the "relevant time period" as defined in the complaint). Defendants did not initially make any allegations of burden or overbreadth, but after reading this section of Relator's response, Defendants added conclusory language to their section claiming their proposed discovery would be "tailored" while Relator is proposing "overly burdensome" nationwide discovery. But even these allegations fall far short of "proof" and do not explain why discovery focused on "a single facility in Texas" during a short, arbitrary timeframe limited only to Florida,

would require nearly a year of discovery, its own expert reports and a carve-out for its own summary judgement motion.

The cases cited by Defendants in which phased discovery was allowed are also either distinguishable or do not support Defendants' position. *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 719 F.3d 31 (1st Cir. 2013), for example, is cited for the proposition that "courts routinely phase discovery to focus initially on the allegations within the relator's personal knowledge," but discovery in *Duxbury* was not limited in time due to the relator's "personal knowledge" but was confined because the relator "qualified as an original source only with regard to allegations concerning the 1992-1998 time period" – a circumstance not present here.

Defendants' citation to *U.S. ex rel. Carpenter v. Abbott Labs., Inc*., 723 F. Supp. 2d 395, 409–10 (D. Mass. 2010), is equally inapposite. *Carpenter* involved off-label prescriptions where the court initially limited discovery to Massachusetts because it was not clear from the complaint that off-label prescriptions were made across the country. *Id*. But the court expressly allowed the relator to expand discovery when he could demonstrate that the scheme was part of a nationwide directive.[4] *Id*., citing *U.S. ex rel. Rost v. Pfizer, Inc*., 253 F.R.D. 11, 17 (D. Mass. 2008) (ROST III) (discovery limited only until relator could make out allegations of a nationwide fraud). Here, the SAC contains detailed allegations that Defendants' Pre-filled Syringe Program was perpetrated nationwide by McKesson, using, among other things, an illegal

[4] *United States v. Medtronic, Inc*., No. 95-1236-MLB, 2000 WL 1478476, at *3 (D. Kan. July 13, 2000), also does not stand for the proposition that discovery should be limited to the region where the relator is located despite allegations of a nationwide fraud. In *Medtronic*, discovery was limited to a certain region only after the court "carefully studied the language of the complaint" and "disagree[d] with [relator's] characterization that he has alleged a claim of 'nationwide' fraud." *Id*.

Texas-based plant and then a Tennessee facility to fraudulently manufacture pre-filled syringes from drug-vial overfill, followed by Defendants' marketing and selling those syringes to physicians nationwide for administration to the country's most vulnerable patients.

Defendants' proposed "phased" discovery is one-sided and will artificially and irrationally limit discovery, resulting in an inefficient, costly and unwieldy discovery process and lead to multiple trials on essentially the same issues, split up only by time and geography. If allowed, their proposal will also unnecessarily prolong the litigation and do nothing to narrow the issues for trial. Relator opposes any motions or other attempts by Defendants to inappropriately limit or "phase" discovery in this action.

Defendants' Statement:

Defendants submit that discovery should be phased, and that Phase I discovery should be limited to (1) underlying conduct occurring from 2007 through 2008, and (2) claims for pre-filled syringes submitted to government healthcare programs by healthcare providers, including Omni, that are located in Florida.[5] Defendants intend to file a formal motion seeking this relief.

Omni's allegations relate to pre-filled syringes that were created at two different facilities during two different time periods. Omni's allegations from 2007 (when Omni alleges that it first gained personal knowledge of the underlying conduct, *see* SAC ¶ 6) until December 1, 2008, relate to syringes that were created at a facility in Texas. On the latter date, the Texas facility was sold to a third party. Thereafter, production moved to a facility in Tennessee, where it remained until it ended in 2010. Because the evidence related to the two facilities—and

[5] Discovery on subjects other than the underlying conduct, such as what the Government knew about that conduct and when it gained that knowledge, would proceed without the proposed temporal limitation.

therefore the two time periods—will be largely distinct, Defendants submit that it would be appropriate to focus discovery initially on one of the two.

In proposing that the first phase of discovery focus on the period from 2007 through 2008, Defendants are guided by the SAC, which includes specific factual allegations only about the Texas facility. In particular, in Paragraph 19, Omni alleges that its "principal" participated in a meeting at the Texas facility on August 28, 2007 at which he "witnessed firsthand" certain alleged conduct that Omni asserts was improper. *See* SAC ¶ 19. The SAC contains no similar allegation regarding the Tennessee facility, and indeed, it includes no specific allegation at all about any conduct at that facility.

Discovery also should be limited initially to claims submitted in Florida, where Omni is located. The SAC purports to encompass claims allegedly submitted to Medicaid agencies in 31 states, and it asserts causes of action arising under state-law analogs to the FCA promulgated in each of those states. Each of the state Medicaid programs is distinct, as is each of the state statutes. It would not be sensible to attempt to litigate claims related to all of these claims, all of these programs, and all of these laws all at once. Rather, a much more reasonable approach is to focus initially on the claims submitted in Florida—where Omni is located—and on the issues raised by Florida law. This limitation is particularly appropriate given that the only allegedly false claims set forth with any specificity in the SAC are the claims that Omni itself submitted in Florida. There are no similarly specific allegations about claims in any other states.

In complex FCA cases such as this, courts routinely phase discovery to focus initially on the allegations within the relator's personal knowledge and those that are alleged with specificity. For example, in *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 719 F.3d 31 (1st Cir. 2013), despite the fact that the complaint made "nationwide allegations," the

First Circuit approved the district court's decision to focus discovery initially on the region in which the relator had "direct experience" and on the single paragraph in the complaint that satisfied Rule 9(b). *See id.* at 39. Numerous other cases have taken a similar approach, often noting the benefits to efficiency and orderly case management of focusing initially on the relator's most specific allegations.[6] A phased approach to FCA discovery also is supported by Rule 26's emphasis on proportionality, which counsels in favor of limiting initial discovery to a representative sample of claims before deciding whether to proceed further. *See United States ex rel. Customs Fraud Investigations v. Victaulic Co.*, 839 F.3d 242, 259 (3d Cir. 2016).

Applying these principles, Defendants' proposed phasing approach will enable the parties to focus efficiently and proportionally on a limited set of factual and legal issues. These issues will relate to a single facility in Texas, a relatively narrow timeframe, and a relatively small sample of claims submitted in Florida. This tailored discovery will be much more reasonable and proportional than the overly burdensome, overbroad, nationwide discovery Omni proposes.

At the close of Phase I discovery, Defendants' proposal will permit the parties to raise key issues for resolution on summary judgment on the basis of a manageable record. The resulting summary judgment rulings may resolve the case, but even if they do not, they will narrow the issues in dispute for any further phase of the action. Thus, following resolution of

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[6] *See, e.g.*, *United States ex rel. Spay v. CVS Caremark Corp.*, 2013 WL 4525226, at *2-3 (E.D. Pa. Aug. 27, 2013) ("In similar situations, where nationwide discovery would be either overbearing or cost-prohibitive, some courts have provided an initial period of limited discovery to regions in which specific false claims had been alleged, while reserving for a later date broader nationwide discovery on claims that were supported only by reasonable inferences drawn from allegations of the complaint.") *United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 409-10 (D. Mass. 2010) (although relator successfully alleged nationwide conduct, "sensible course" was to limit initial discovery to claims submitted in one state); *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 17 (D. Mass. 2008) (limiting initial discovery to geographic region as to which relator made specific factual allegations); *United States ex rel. Regan v. Medtronic, Inc.*, 2000 WL 1478476, *4 (D. Kan. Jul. 13, 2000) (limiting discovery to geographic area and time period in which relator personally observed alleged conduct).

Phase I summary judgment motions, the parties and the Court will be in a position to determine the appropriate scope of the future phases of the case, if any. Contrary to Omni's assertion, Defendants do not propose 31 phases of discovery. The number and scope of any additional phases will depend on the outcome of Phase I, but in no event do Defendants envision anything approaching 31 phases of this action.

Defendants will soon file an appropriate motion formally requesting that discovery be phased and that it be limited initially as outlined above.[7]

C. Any issues about disclosure, discovery, or preservation of electronically stored information, including the form or forms in which it should be produced

The parties may possess electronically stored information that may be relevant to the claims and defenses in this action. The parties intend to address the form(s) in which electronically stored information should be produced in their discovery requests and responses.

D. Any issues about claims of privilege or of protection as trial-preparation materials, including—if the parties agree on a procedure to assert these claims after production—whether to ask the court to include their agreement in an order under Federal rule of Evidence 502

Neither party seeks an order under Federal Rule of Evidence 502.

E. What changes should be made in the limitations on discovery imposed under these rules or by local rule, and what other limitations should be imposed

Neither party seeks changes to the limitations on discovery imposed under the Federal Rules of Civil Procedure or the local rules of this Court.

[7] Omni makes various allegations about the timing of the parties' revisions to the present document. None of those allegations bear on the issues for the Court's consideration.

F. Any other orders that the court should issue under Rule 26(c) or under Rule 16(b) and (c)

The parties agree a protective order is appropriate to protect the identity of personally-identifiable health information and confidential and proprietary business information. The parties will work together to propose a stipulated form of order for the Court's review.

To avoid delay in producing documents, the parties agree to produce privilege logs within a reasonable time after production of the documents, taking into account the volume of the documents. *Cf.* L.R. 26.2(b).

Dated: March 27, 2019

Respectfully submitted,

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